

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

## Remarks

### **Rejection of Claims 1-17 and 19-37 Under 35 U.S.C. 103(a)**

Claims 1-17 and 19-37 stand rejected under 35 U.S.C. 103(a) as allegedly obvious over EP 0 521 562 in view of EP 0 678 295, EP 0 159 237, GB 2002319, and JP05194253. The Applicants maintain their previous arguments regarding the cited art and traverse the Office Actions assertions regarding the teachings of the cited art. Based upon these arguments alone, the claims are non-obvious in view of the cited art.

The pending claims are drawn to powders of reversed vesicles and processes of making the powders. The powders of reversed vesicles comprise one or more non-ionic surfactants, whereby when the powder is dispersed in a biodegradable oil the percent yield of reversed vesicles is greater than when the same amount of reversed vesicles is prepared directly in the biodegradable oil.

In a Response mailed on April 4, 2003, the Applicants presented arguments that the claimed compositions and methods are non-obvious over, *inter alia*, the EP 562 reference because they possess an unexpected property.

The Office asserts that the prior art does not suggest the use of biodegradable oil in the preparation of vesicles and that EP 562 teaches the use of "synthetic oil just as in the instant application." The Office concludes that it is therefore unclear how the pending claims overcome the rejection over EP 562 and how the compositions and methods are to be considered as possessing unexpected properties.

The Office appears to argue that Applicants' evidence of unexpected properties is of no consequence because the prior art does not suggest the use of biodegradable oils in the preparation of vesicles. But this argument rather strengthens the Applicant's position as it indicates that the prior art has even fewer teachings related to reversed vesicles and biodegradable oils and, therefore, makes the applicants' discovery of the recited property even more non-obvious over the cited art.

Nevertheless, the EP 562 reference, contrary to the Office's assertion, teaches a number of biodegradable oils that can be used for the preparation of dispersions (not powders) of reversed vesicles. For example, EP 562 teaches that suitable non-polar excipients include glycerol triesters of higher saturated and unsaturated fatty acids having 10-30 carbon atoms, such as glyceryltrilaurate and hydrogenated castor oil, and vegetable oils such as coconut oil and peanut oil. See EP 562, paragraph spanning columns 9 and 10.

Thus, the applicant's reiterate their position that the claimed compositions and methods are non-obvious over EP 562 (and the other cited references) because they possess an unexpected property. When the claimed powders are dispersed in a biodegradable oil the percent yield of reversed vesicles is greater than when the same amount of reversed vesicles is prepared directly in the biodegradable oil. See specification, page 2, lines 10-14; and Examples 3-5. Such a property is nowhere taught, suggested, or contemplated by any of the cited references. The presence of a property not possessed by the prior art is evidence of non-obviousness. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963); MPEP § 716.02(a). The applicants respectfully submit that this unexpected property renders the claimed compositions and processes non-obvious.

The Office has asserted that the EP 562 reference teaches the use of "synthetic oil just as in the instant application," and contends that it is unclear how the pending claims overcome the rejection over EP 562. The vesicular preparation of EP 562 is a dispersion whereas the instant claims are directed to a powder. When the claimed powders are dispersed in a biodegradable oil the percent yield of reversed vesicles is greater than when the same amount of reversed vesicles is prepared directly in the biodegradable oil. It is the powder (and method for making it) and not the dispersion that possesses the unexpected properties. EP 562 fails to teach or suggest a powder and fails to teach or suggest the unexpected property of such a powder observed by the applicants.

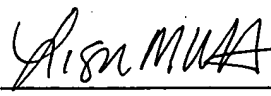
The other references cited by the Office do not remedy the deficiencies of the teachings of the EP 562 reference. They do not teach or suggest powders of reversed vesicles that comprise one or more non-ionic surfactants (or processes of making the powders). And they do not teach or suggest the unexpected properties of the powders of reversed vesicles.

For all of the foregoing reasons, the applicants respectfully request reconsideration and withdrawal of this § 103 rejection.

If the Examiner believes that a telephone or personal interview would expedite prosecution of the instant application, the Examiner is invited to call the undersigned attorney at (312) 913-2135.

Respectfully submitted,  
**McDonnell Boehnen Hulbert & Berghoff**

Date: October 24, 2003

By:  REG No. 43,673  
FCR Michael S. Greenfield  
Reg. No. 37,142